In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-258V

Filed: May 9, 2016

LAUREN NATALIE LEE,	*	TO BE PUBLISHED
	*	
Petitioner,	*	Special Master Hamilton-Fieldman
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Gardasil; Human Papillomavirus (HPV) Vaccine; Statute of Limitations; Premature Ovarian Failure (POF); Primary Ovarian Insufficiency (POI); First Symptom or Manifestation of Onset; Menstrual Cycle; Dismissal.
Respondent.	*	

Mark Krueger, Krueger & Hernandez, SC, Baraboo, WI, for Petitioner.
Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION[1]

This is an action by Lauren Lee ("Petitioner") seeking an award under the National Vaccine Injury Compensation Program (hereinafter "Program").[2] Respondent contends that the petition was untimely filed, and as such should be dismissed. For the reasons set forth below, the undersigned concludes that the petition was untimely filed, and it is therefore hereby dismissed.

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (hereinafter "Vaccine Act"), provides the statutory provisions governing the Program.

I. FACTUAL BACKGROUND

Petitioner was born on October 13, 1982. Pet'r's Ex. 1 at 1, ECF No. 6-2. When she was 10, in 1992 or 1993, Petitioner experienced menarche.[3] Pet'r's Ex. 2 at 10-11, ECF No. 6-3. For the next nine years, Petitioner's menstrual cycles were irregular. *Id.*

In 2001 or 2002, a doctor prescribed Petitioner hormonal oral contraceptive pills ("OCPs").[4] *Id.*; *see* Pet'r's Ex. 6 at 10, ECF No. 15-3. Petitioner began to bleed regularly. Pet'r's Ex. 2 at 10; *see* Pet'r's Ex. 6 at 6.

Sometime between then and May of 2005,[5] Petitioner stopped taking the OCPs and her menstruation again became irregular. *See* Pet'r's Ex. 2 at 10, 28. On May 23, 2005, Petitioner sought OCPs from her physician. *Id.* at 28. Between then and August 22, 2006, Petitioner suffered from irregular menstruation. *Id.* at 28, 32. Petitioner averred in her affidavit that she "starting taking [] birth control . . . to regulate [her] menses" sometime in 2006. Pet'r's Ex. 1 at 1.

In November and December of 2006 and April of 2007, Petitioner received three doses of the HPV vaccine. *Id.* Despite taking OCPs, Petitioner noted in November of 2008 and May of 2008 that her bleeding was irregular. Pet'r's Ex. 2 at 25, 27.

In August of 2012, Petitioner ceased taking OCPs due to headaches. Pet'r's Ex. 1 at 1. Petitioner experienced one more menstrual cycle and then stopped menstruating altogether. Pet'r's Ex. 2 at 7.

Notably, at a visit on December 4, 2012, a physician summarized Petitioner's menstrual history as follows. *See id.* at 10. Petitioner experienced menarche at age 10. *Id.* She then

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[3] Menarche is "the establishment or beginning of menstruation." Menarche, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*"). Menstruation is "the cyclic, physiologic discharge through the vagina of blood and mucosal tissues from the nonpregnant uterus; it is under hormonal control and normally recurs, usually at approximately four-week intervals, in the absence of pregnancy during the reproductive period (puberty through menopause) of the female of the human." Menstruation, *Dorland's*.

[4] The medical records do not establish whether OCPs that were prescribed in 2001 or 2002 were intended to regulate Petitioner's menses or whether, alternatively, they were prescribed for contraceptive purposes.

[5] The undersigned observes that Petitioner's medical records do not clearly provide when she started and stopped ingesting OCPs.

endured irregular menstruation until age 19, when she began OCPs. *Id.* At age 21, she stopped taking OCPs and again suffered irregular menstruation until age 25. *Id.* At that time, she began taking new OCPs; but in August 2012, she stopped doing so because they caused migraines. *Id.* Between then and December 4, she did not menstruate. *Id.*

In January of 2013, a physician observed an elevated level of FSH, which was indicative of primary ovarian insufficiency ("POI").[6] Pet'r's Ex. 4 at 19, ECF No. 6-5. By August, Petitioner was experiencing numerous hot flashes and had been diagnosed with POI by two different physicians. Pet'r's Ex. 10 at 2, ECF No. 23-2; Pet'r's Ex. 4 at 2, 9-10. Petitioner underwent a series of genetic tests, none of which revealed any abnormalities. Pet'r's Ex. 10 at 6, 11; Pet'r's Ex. 4 at 11.

Petitioner's most recent medical records reveal that she continues to endure irregular bleeding, despite hormonal supplementation. Pet'r's Ex. 11 at 2, ECF No. 23-3.

II. PROCEDURAL BACKGROUND

On April 2, 2014, Petitioner filed the present action alleging that the Human Papillomavirus vaccinations ("Gardasil" or "HPV" vaccines) administered to her in October and November 2006 and in April 2007, caused her to suffer from POI. Pet., ECF No. 1.

This case was identified for inclusion with other POI cases in an "omnibus proceeding" established to address the question of what constitutes the first symptom or manifestation of POI. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*, ECF No. 23. The answer to this question is integral to the undersigned's determination of whether each petitioner had filed her claim within the statute of limitations. *See* 42 U.S.C. § 300aa-16(a)(2) (2012) (requiring that petitions be filed prior to "the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of injury").

[6] Although the parties and the undersigned initially used the term "premature ovarian failure" or "POF" to define Petitioner's injury, it became clear from the literature filed by the experts that POI "is the preferred term for the condition that was previously referred to as [POF]. . . . The condition is considered to be present when a woman who is less than 40 years old has had amenorrhea for 4 months or more, with two serum FSH levels (obtained at least 1 month apart) in the menopausal range." *See* Pet'r's Ex. 15, Tab 1 at 1, *Culligan v. Sec'y of HHS*, No. 14-318V, ECF No. 53-2 (Lawrence Nelson, *Primary Ovarian Insufficiency*, 360 New Eng. J. Med. 606, 606 (2009)) (hereinafter "Nelson" with pincites to Petitioner's pagination); *see also* Resp't's Ex. A.29, *Culligan*, ECF No. 67-1 (also providing Nelson). Therefore, the undersigned will refer to the condition as POI.

The lead case in the proceeding was *Culligan.*[7] In *Culligan*, Respondent opposed entitlement to compensation because the first symptom of the petitioner's POI was oligomenorrhea,[8] which she had experienced more than three years prior to the filing of her claim, making it untimely under 42 U.S.C. § 300aa-16(a)(2). *See* Resp't's Rule 4(c) Report at 3-4, *Culligan*, ECF No. 20.

At a *Culligan* status conference held on September 23, 2014, the undersigned discussed with the parties the necessity of establishing the date that the statute of limitations began to run in *Culligan* and other cases alleging an injury of POI caused by Gardasil in order to assess the timeliness of the claims. *See* Scheduling Order (Sept. 25, 2014) at 1, *Culligan*, ECF No. 22. The undersigned directed the petitioner in *Culligan*'s counsel, Mark Krueger, who is also counsel in the instant case, to begin the process of identifying other POI claimants for inclusion in an omnibus proceeding focused on the question of timeliness.[9] *Id*.

On October 1, 2014, Mr. Krueger filed a status report in which he identified eight POI cases[10] to be included in the undersigned's assessment of timeliness. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*. Petitioner subsequently named *Culligan* as the "test case" for timeliness. *See* Pet'r's Status Report (Nov. 5, 2014) at 1, ECF No. 25.

Another status conference was held on November 20, 2014, during which the parties agreed that "in all pending [POI] cases . . . an expert hearing [would] be held to address the question of what constitutes 'the first symptom or manifestation of [POI] onset recognized as such by the medical profession at large.'" Scheduling Order (Nov. 24, 2014) at 1, *Culligan*, ECF No. 26 (citing *Cloer v. Sec'y of HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc)). The undersigned explained that a timeliness determination would be made on the basis of the

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[7] Once *Culligan* had been designated as the lead case, all of the filings for the onset proceedings were completed in the *Culligan* case, and not in the trailing cases. This section of the procedural history is therefore derived from the *Culligan* case. Citations to the *Culligan* record are so noted.

[8] Oligomenorrhea is defined as "menstrual flow happening less often than normal, defined as at intervals of 35 days to 6 months; called also *infrequent menstruation*." Oligomenorrhea, *Dorland's*.

[9] Mr. Krueger is counsel for all but one of the petitioners in the omnibus proceeding.

[10] Other than the instant case, Petitioner identified *Culligan*; *Alexander v. Sec'y of HHS*, 14-868V; *Tilley v. Sec'y of HHS*, 14-818V; *Fishkis v. Sec'y of HHS*, 14-527V; *Lydia McSherry v. Sec'y of HHS*, 14-154V; *Meghan McSherry v. Sec'y of HHS*, 14-153V; *Stone v. Sec'y of HHS*, 13-289V. Pet'r's Status Report (Oct. 1, 2014) at 1, ECF No. 23.

evidence presented at the *Culligan* hearing; similar hearings would *not* be conducted in the other POI cases, all of which would trail *Culligan* for purposes of timeliness determinations. *Id*. The undersigned also added four additional POI cases[11] to the list of cases set to trail *Culligan*. *Id*. The undersigned also ordered that all parties seeking to be joined in the omnibus proceeding consent to share their medical records, *see* Scheduling Order (Nov. 24, 2014) at 2, *Culligan*, and all parties later obliged.

The parties and the undersigned proceeded to identify questions for the experts (to be researched and answered before the hearing) regarding the nature and timing of the first symptom or manifestation of onset of POI in the aforementioned cases. *See, e.g.*, Order (Feb. 18, 2015) at 1, *Culligan*, ECF No. 37; Scheduling Order (Jan. 30, 2015) at 1, *Culligan*, ECF No. 36; Pet'r's Status Report (Dec. 29, 2014) at 1, *Culligan*, ECF No. 31; Scheduling Order (Nov. 24, 2014) at 2, *Culligan*; Resp't's Status Report (Oct. 28, 2014) at 1, *Culligan,* ECF No. 24. The parties and their experts ultimately agreed that, except in *Culligan*, in which the entire medical record would be considered by the experts, the experts would "offer opinions regarding the onset issues in the trailing cases by considering the facts of those cases as hypotheticals." Joint Status Report (Jan. 20, 2015) at 1, *Culligan*, ECF No. 33. To facilitate this process, Petitioner filed summaries of the facts of all twelve POI cases. *See* Pet'r's Ex. 9, *Culligan*, ECF No. 34-2.[12] Except in *Culligan*, the experts were to rely on the factual summaries, in lieu of the medical records themselves, to articulate their opinions regarding timeliness. *See* Joint Status Report (Jan. 20, 2015) at 1, *Culligan*.

At a status conference held on January 28, 2015, the undersigned set deadlines for the parties' expert reports regarding timeliness. *See* Order (Jan. 30, 2015) at 2, *Culligan*. The experts were directed to address all of the identified timeliness questions separately, "on a question-by-question basis." *Id*. at 1.

On February 19 and March 3, 2015, three additional cases,[13] all filed by Mr. Krueger, were added to the list of POI trailing cases. *See* Scheduling Order (Mar. 3, 2015) at 1, *Culligan*,

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[11] The four added cases were *Chenowith v. Sec'y of HHS*, 14-996V; *Bello v. Sec'y of HHS*, 13-349V; *Olivia Meylor v. Sec'y of HHS*, 10-771V; *Madelyne Meylor v. Sec'y of HHS*, 10-770V. *Id.* The petitioners in these cases were all represented by Mr. Krueger.

[12] A factual summary for another trailing POF case–*Smith*, 14-1107V –was also filed in *Culligan*. *See* Order Appendix (Feb. 23, 2015) at 2-3, *Culligan*, ECF No. 39-1; *see also* Order (Jan. 30, 2015) at 1-2, *Culligan*, ECF No. 36; Order (Jan. 26, 2015), *Culligan*, ECF No. 35. The petitioner in *Smith* was represented by different counsel.

[13] The cases were *Brayboy v. Sec'y of HHS*, 15-183V; *Garner v. Sec'y of HHS*, 15-143V; and *Vakalis v. Sec'y of HHS*, 15-134V.

ECF No. 45; Scheduling Order (Feb. 19, 2015) at 1, *Culligan*, ECF No. 38. Mr. Krueger subsequently filed factual summaries of the three new cases. *See* Pet'r's Exs. 10, 11, 12, *Culligan*, ECF Nos. 40-2, 41-2, 44-2.

On March 12, March 13, and April 29, 2015, Petitioner filed expert reports and supporting medical literature, all of which were purportedly limited to the issue of timeliness. *See* Pet'r's Ex. 13, *Culligan*, ECF Nos. 47-2 to 51-6; Pet'r's Ex. 15, *Culligan*, ECF Nos. 53-1 to 54-3; Pet'r's Ex. 17, *Culligan*.[14] The expert reports were authored by Dr. Felice Gersh and Dr. Orit Pinhas-Hamiel. *See* Pet'r's Ex. 13, Tab 1, *Culligan*; Pet'r's Ex. 15, Tab 1, *Culligan*. The reports filed by Drs. Gersh and Hamiel reflected that they had reviewed the medical records underlying all of the POI cases. *See* Pet'r's Ex. 13, Tab 1 at 12-13, *Culligan*; Pet'r's Ex. 15, Tab 1 at 17, *Culligan*.

The undersigned convened a status conference on April 1, 2015, after having reviewed Petitioner's expert reports. *See* Scheduling Order (Apr. 2, 2015) at 1, *Culligan,* ECF No. 55. The undersigned noted that, "notwithstanding the fact that Petitioner's onset experts have now reviewed the medical records associated with every [POI] case, Respondent's onset expert(s) will review only the cases' factual summaries, the *Culligan* record, and Respondent's list of hypothetical questions." *Id*. Also, having expressed some concern about the extent to which Petitioner's expert reports reflected an understanding of the relevant question regarding timeliness, the undersigned reiterated the following:

> [T]he relevant date, for purposes of assessing onset under *Cloer*, is *not* the first point in time at which a definitive diagnosis could have been made; rather, it is the time at which the first symptom or manifestation of the allegedly vaccine-caused injury occurred. The onset experts must make this assessment with the benefit of hindsight, rather than placing themselves in the shoes of the treating, diagnosing physicians. The parties are directed to address this issue as specifically as possible in their pre-hearing briefs.

Id. (full citation omitted).

Respondent then filed an expert report regarding timeliness, as well as relevant medical literature, on May 8, May 28, and June 1, 2015. Resp't's Ex. A to A.32, *Culligan,* ECF Nos. 57-1 to 59-6, 63-1 to 63-3, 66-1 to 67-4. Respondent's expert report was authored by Dr. David Frankfurter. Resp't's Ex. A at 6, *Culligan*.

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[14] Petitioner filed Exhibit 17 via compact disc. *See* Notice of Intent to File on Compact Disc (Apr. 29, 2015), *Culligan*, ECF No. 56.

At a status conference held on May 14, 2015, Respondent confirmed that, in preparing his expert report, Dr. Frankfurter had reviewed only the factual summaries submitted by Petitioner (and the medical record from *Culligan*). *See* Order (May 15, 2015) at 1, *Culligan,* ECF No. 61. Mr. Krueger agreed that, notwithstanding the fact that his experts had reviewed all of the medical records in all of the POI cases, "his experts would be referring to the factual summaries rather than to the medical records themselves" at the timeliness hearing. *Id*.

The parties filed their pre-hearing briefs simultaneously on June 1, 2015, *see* Pet'r's Prehearing Submissions, *Culligan,* ECF No. 65; Resp't's Prehearing Submissions, *Culligan,* ECF No. 69; and the hearing took place on June 16 and 17, 2015, *see* Minute Entry (June 18, 2015), *Culligan*. Petitioner's experts, Drs. Gersh and Hamiel, and Respondent's expert, Dr. Frankfurter, testified. Tr. at 4, 255, *Culligan,* ECF Nos. 81, 83.

On July 1, 2015, the undersigned issued an order identifying nine POI cases[15] "as presumptively precluded under the applicable statute of limitations." Order (July 1, 2015) at 1, *Culligan,* ECF No. 79. *Culligan* was included among the presumptively precluded cases. *Id*. The undersigned also identified six cases[16] that appeared to have been timely filed. *Id*. Having apprised the parties of these preliminary conclusions, the undersigned granted them additional time to file status reports identifying the cases in which they intended to contest this determination, and explaining what they had identified as the first symptom or manifestation of onset in each of those cases. *Id*. at 2.

On August 28, 2015, Respondent filed a status report in which she stated that she did not intend to contest the undersigned's preliminary findings in any of the presumptively timely cases filed by Mr. Krueger. Resp't's Status Report (Aug. 28, 2015) at 1, *Culligan,* ECF No. 84. In status reports filed on September 2 and 30, 2015, Petitioner argued that all of the preliminarily precluded cases were, in fact, timely. *See* Pet'r's Status Report (Sept. 2, 2015) at 2-7, *Culligan*, ECF No. 85 (addressing *Culligan*, *Chenowith*, *Garner*, *Lee*, *Lydia McSherry*, and *Madelyne Meylor*); Pet'r's Status Report (Sept. 30, 2015) at 1-2, *Culligan,* ECF No. 87 (addressing *Fishkis*, *Meghan McSherry*, *Stone*).

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[15] The instant case, as well as *Culligan*, *Chenowith*, *Fishkis*, *Garner*, *Lydia McSherry*, *Meghan McSherry*, *Madelyne Meylor*, and *Laughlin*. Order (July 1, 2015) at 1.

[16] *Alexander*, *Bello*, *Brayboy*, *Olivia Meylor*, and *Vakalis*. *Id.* The undersigned also identified as timely *Smith*, a trailing POF case that had been filed by a different attorney. *Id.* In *Tilley*, the undersigned directed the parties to file additional briefs regarding timeliness. *Id.*

At a status conference held on October 13, 2015, the undersigned "informed the parties that, for purposes of an onset determination, the [POI] cases [would] be divided [into] two groups: petitioners who never menstruated . . . and the rest of the [POI] petitioners." *See* Scheduling Order (Oct. 14, 2015) at 1, *Culligan,* ECF No. 88.

Relevant post-hearing briefing[17] concluded on January 20, 2016. *See* Pet'r's Post Hr'g Br., *Culligan,* ECF No. 91; Resp't's Post Hr'g Brs., *Culligan,* ECF No. 94; Pet'r's Post Hr'g Reply Br., *Culligan,* ECF No. 95. Petitioner's claim is now ready for a determination of the first symptom or manifestation of onset of the alleged vaccine-related injury; and, relatedly, whether the Vaccine Act's statute of limitations bars the claim.

III. ANALYSIS

A. Applicable Legal Standard

Section 300aa-16(a)(2) of the Vaccine Act provides that, regarding

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1998], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.

42 U.S.C. § 300aa-16(a)(2).

This statute of limitations is not triggered by the administration of the vaccine, but "begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought." *Cloer*, 654 F.3d at 1335. "[E]ither a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first." *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

"[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations." *Carson ex rel. Carson v. Sec'y of HHS*, 727 F.3d 1365, 1369 (Fed. Cir. 2013), *reh'g & reh'g en banc denied*, 2013 WL 4528833 at *1. "A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." *Markovich*, 477 F.3d at 1357. While the symptom of an injury must be recognized as such "by the medical profession at large," *Cloer*,

[17] Briefing addressing Petitioner's request for interim attorneys' fees is not relevant to the timeliness issue and is therefore not included in this discussion.

654 F.3d at 1335, even subtle symptoms that a petitioner would recognize "'only with the benefit of hindsight, after a doctor makes a definitive diagnosis of injury,'" trigger the running of the statute of limitations, whether or not the petitioner or even multiple medical providers understood their significance *at the time*. *Carson*, 727 F.3d at 1369-70 (quoting *Markovich*, 477 F.3d at 1358).[18]

There is no explicit or implied discovery rule under the Vaccine Act. *Cloer,* 654 F.3d at 1337. The date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine-related injury "does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Id.* at 1339. Nor does it depend on when a petitioner knew or should have known of a potential connection between an injury and a vaccine. *Id.* at 1338 ("Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury."); *see Markovich*, 477 F.3d at 1358 ("Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." (internal quotation marks omitted)).

B. Symptoms of POI Onset, Including Criteria for Distinguishing "Symptom" from "Normal"

Primary ovarian insufficiency can begin abruptly, *see* Tr. at 69; *see also* Nelson at 2-3; but it may also develop over several years, *see* Tr. at 70, 198-99, 398; *see also* Nelson at 2-3; Pet'r's Ex. 17, Tab 50 at 2 (Paolo Beck-Peccaz & Luca Persam, *Premature Ovarian Failure*, 1 Orphanet J. Rare Diseases, at 2 (Apr. 2006)) (hereinafter "Beck-Peccaz"). Thus, a woman could have symptoms of POI for several years before actually ceasing menstruation or being diagnosed with POI. *See* Tr. at 70, 198-99, 398*; see also* Tr. at 319; Nelson at 2-3; Beck-Peccaz at 2. The experts agreed that the symptoms of primary ovarian insufficiency include menstrual

[18] Petitioner argues that "POI is a latent injury" and that "the first symptom of onset, in terms of the applications [sic] of the statute of limitations, can be subtle and can precede manifestation of onset by months or even years." Pet'r's Post Hr'g. Br. at 9. This argument has been made before: the Court of Federal Claims, in *Setnes v. United States*, 57 Fed. Cl. 175 (2003), "was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms 'symptom' and 'manifestation.'" *Markovitch*, 477 F.3d at 1357-58. The *Setnes* court's interpretation of the "first symptom or manifestation of onset" language of the statute was rejected by *Markovich*, a ruling that has since been reaffirmed by the Federal Circuit en banc in *Cloer*. 654 F.3d at 1334-1335.

irregularities, including primary and secondary amenorrhea,[19] cycle and frequency irregularity, and excessive or prolonged bleeding; delayed menarche; lack of breast development and poor growth velocity; night sweats; hot flashes; sleep disturbances; mood changes; recurring ovarian cysts; arrested puberty; and marked hirsutism. Tr. at 38, 57, 68-69, 319, 366. Most of these symptoms are not "normal" for a woman under the age of 40. Petitioner therefore does not dispute that they can constitute the "first symptom or manifestation of onset" of POI for purposes of the Act's statute of limitations, and there was little discussion of the symptoms beyond their inclusion on the list of symptoms. As to menstrual irregularities and delayed menarche, however, Petitioner and Petitioner's experts dispute that these two conditions should be considered symptoms at all, because many young women experience these conditions at the beginning of their reproductive lives, such that these conditions are considered "normal." *See, e.g.,* Pet'r's Post Hr'g Br. at 2, 4-8; Tr. at 32, 58, 61, 72-73, 170-71; *see also* Tr. at 380 (Respondent's expert, Dr. Frankfurter, explaining that it is normal for a teenager to have irregularity, albeit within a range). As a result, Petitioner and her experts claim, menstrual irregularity only constitutes a symptom or manifestation of onset of POI when that irregularity is effectively considered secondary amenorrhea. Pet'r's Post Hr'g Br. at 4-5; Pet'r's Post Hr'g Rep. Br. at 3.

By instead finding that "normal" menstrual irregularity is a symptom for purposes of the Act's statute of limitations, Petitioner argues, the undersigned will somehow increase Petitioner's burden of proof. *See* Pet'r's Post Hr'g Reply Br. at 1-2. The undersigned does not agree. The undersigned does agree, however, that to qualify as the first symptom or manifestation of onset under the Act, a condition must be a symptom of something amiss, however subtle; it cannot be "normal": a symptom is "[a]ny morbid phenomenon *or departure from the normal* in structure, function, or sensation, experienced by the patient and indicative of disease." Symptom, *Stedman's Medical Dictionary* (28th Ed. 2013) (hereinafter "*Stedman's*") (emphasis added); *accord Markovich*, 477 F.3d at 1360 (observing that eye blinking episodes constituting first symptom of child's seizure disorder "were not normal child behavior"). In order to determine the date of the first symptom or manifestation of onset of the vaccine-related injury, therefore, a method for separating "normal" menstrual irregularities from abnormal symptoms of POI is necessary.[20]

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[19] Amenorrhea is "absence or abnormal stoppage of the menses." Amenorrhea, *Dorland's*. Primary amenorrhea is "failure of menstruation to occur at puberty." Primary Amenorrhea, *Dorland's*. Secondary amenorrhea is "cessation of menstruation after it has once been established at puberty." Secondary Amenorrhea, *Dorland's*.

[20] Petitioner also argues that irregular menstruation should not be considered the first symptom of POI because it "can be explained by other causes." Pet'r's Post Hr'g Reply Br. at 2-3. This argument has been repeatedly rejected by the Federal Circuit, and is equally as unpersuasive here. A symptom need not be exclusive to the particular injury alleged in order to be "the first

Fortunately, medical literature provided by the parties provides a solution, both simple and elegant. *See* Resp't's Ex. A.2, ECF No. 57-4 (Comm. on Adolescent Health Care, Am. Coll. of Obstetricians & Gynecologists, *Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign*, Comm. Op. No. 349 (Nov. 2006)) (hereinafter "ACOG Opinion" or "ACOG Op."); *see also* Pet'r's Ex. 15, Tab 4. In *Cloer* and *Markovich*, the Federal Circuit directed that "the symptom or manifestation of onset must be recognized as such by the medical profession at large." *Cloer*, 654 F.3d at 1335; *Markovich*, 477 F.3d at 1360. The ACOG Opinion is an opinion from the Committee on Adolescent Healthcare at the American College of Obstetricians and Gynecologists, together with the American Academy of Pediatrics, entitled "Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign." *See* ACOG Op. It was issued in November 2006, and "Reaffirmed" in 2009. ACOG Op. at 1. The abstract of the ACOG Opinion provides:

> It is . . . important for clinicians to have an understanding of bleeding patterns in girls and adolescents, the ability to differentiate between normal and abnormal menstruation, and the skill to know how to evaluate young patients' conditions appropriately. Using the menstrual cycle as an additional vital sign adds a powerful tool to the assessment of normal development and the exclusion of serious pathologic conditions.

Id. The article goes on to discuss a number of articles and robust epidemiological studies concerning what constitutes "normal menstrual cycles in young females," including age at menarche, and "cycle length and ovulation," *id.* at 2-3; "abnormal menstrual cycles," including "prolonged interval[s]," *id.* at 3-4; and "excessive menstrual flow," *id.* at 4. The article concludes with a chart, reproduced below, that together with one difference applicable to women older than 18, provides comprehensive guidance to the "medical profession at large" about when menstrual irregularities have exceeded "normal" variation to become symptoms of a potential problem. *Id.* at 4-5. The chart is as follows:

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symptom" of that injury for purposes of the Act. *See Markovich*, 477 F.3d at 1357 ("A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the significance of a symptom with regard to a particular injury."); *see also Carson*, 727 F.3d at 1370 (holding that even where "[t]here is no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal . . . it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism, the alleged vaccine injury.")

Menstrual Conditions That May Require Evaluation

Menstrual periods that:

- Have not started within 3 years of thelarche[21]
- Have not started by 13 years of age with no signs of pubertal development[22]
- Have not started by 14 years of age with signs of hirsutism[23]
- Have not started by 14 years of age with a history or examination suggestive of excessive exercise or eating disorder
- Have not started by 14 years of age with concerns about genital outflow tract obstruction or anomaly
- Have not started by 15 years of age[24]
- Are regular, occurring monthly, and then become markedly irregular[25]

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[21] Thelarche is "the beginning of development of breasts in the female." Thelarche, *Stedman's*.

[22] Pubertal development is measured by assessing an individual's stages of puberty using the Tanner growth chart, which is "based on pubic hair growth, development of genitalia in boys, and breast development in girls." Tanner stage, *Stedman's*. For purposes of the ACOG criteria, the undersigned considers Tanner stages I (child) and II (prepubertal) as showing "no signs of pubertal development," and Tanner stags III (early pubescent) and IV (late pubescent) as showing such signs. Dr. Frankfurter testified that a young woman who has never menstruated and who has no signs of secondary sexual development by age 13 should be evaluated. Tr. at 377.

[23] Hirsutism is the "presence of excessive bodily and facial hair, usually in a male pattern, especially in women." Hirsutism, *Stedman's.*

[24] At the hearing, Doctors Hamiel and Gersh opined that an adolescent who has not reached menarche by age 16 should be evaluated for primary amenorrhea. Tr. at 92, 238. Dr. Frankfurter opined that the age of evaluation should be 15 years. Tr. at 365. Both the ACOG Opinion and Dr. Hillard, author of medical literature introduced by Petitioner, acknowledge that the traditional definition of primary amenorrhea has been no menarche by age 16. ACOG Op. at 2; Pet'r's Ex. 15, Tab 4, at 5, ECF No. 53-5 (Hillard, Paula, *Menstruation in Adolescents: What Do We Know? and What Do We Do with the Information?*, 27 J. Pediatric Adolescent Gynecology 309 (2014)) (hereinafter "Hillard" with pincites to Petitioner's pagination). However, both articles note that 95-98% of females will have experienced menarche by age 15, and that delays in evaluating these young women can result in delays in detection and treatment of significant disorders, including POI. ACOG Op. at 2; Hillard at 6.

[25] At the hearing, Dr. Hamiel testified that she would recommend further evaluation of a non-adolescent woman whose cycle had been regular (21-35 days) and then became irregular (less frequent than every 35 days). Tr. at 67.

- Occur more frequently than every 21 days or less frequently than every 45 days[26]
- Occur 90 days apart even for one cycle[27]
- Last more than 7 days
- Require frequent pad or tampon changes (soaking more than one every 1-2 hours)

Id. at 5.

Hillard reproduces this chart, accompanied with this caution:

> Failure to evaluate teens who meet the criteria cited in the [ACOG] Opinion can be a significant disservice to young women, leading to unnecessary discomfort, embarrassment, poorer quality of life, adverse self esteem, and current or future health risks such as anemia and low bone mineral density, as well as potential metabolic and cardiovascular risks. . . . [J]ust as with other vital signs like pulse and respiration, *[menstrual cycle] values outside of statistically derived normal parameters may signal disease or derangements in normal health.*

Hillard at 8 (emphasis added).

There cannot be a better vehicle for the undersigned to use to sort out "normal" from "symptom" than one designed for that purpose by members of the medical profession themselves. Thus, the undersigned finds that for petitioners who were eighteen years old or younger at the time the condition arose, if the condition qualifies for evaluation on the ACOG chart, it constitutes a symptom for purposes of the Vaccine Act. For petitioners who were over eighteen years old at the time the condition arose, the chart also applies, except that periods that should be evaluated include those that occur more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3.[28]

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[26] For women over the age of 18, this criterion is more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3; *see also* Tr. at 39 (documenting Dr. Hamiel's testimony normal menstrual frequency for a woman in her twenties is 21-35 days). The undersigned interprets this criterion to apply to frequency over two or more cycles.

[27] At the hearing, Dr. Hamiel testified that no menstruation for 90 days is not "normal." Tr. at 79.

[28] To the extent Petitioner argues that this interpretation of the Vaccine Act's statute of limitations violates the Fifth Amendment on Equal Protection and Due Process Grounds, *see* Pet'r's Post Hr'g Br. at 11-13, the undersigned concurs with the reasoning articulated in numerous decisions to the contrary, all of which hold that the Act's statute of limitations does

Finally, as to contraceptives' impact on this analysis, Hillard specifically limited her discussion "only to bleeding on young women who are *not* taking any hormonal therapy such as birth control." Hillard at 6. All of the experts at the hearing agreed that hormonal therapy would mask POI symptoms. Tr. at 115, 161, 387-88. The ACOG Opinion recommends blood collection for screening before hormonal treatment is begun, ACOG Op. at 4, as did Doctors Hamiel, Tr. at 95-97, and Frankfurter, Tr. at 377, at the hearing; although, both experts acknowledged that such testing is often not performed before hormonal treatment is started. Tr. at 95-97, 112-13, 387-92.

Based on that information, the undersigned makes the following findings regarding how contraceptive use will inform the undersigned's findings on onset for purposes of the statute of limitations:[29]

1. If the form of contraceptive used was non-hormonal, i.e., a copper IUD without hormones,[30] condom/diaphragm, spermicide, the ACOG criteria apply as discussed above, without changes;
2. By definition, a contraceptive is "an agent that diminishes the likelihood of or prevents conception." Contraceptive, *Dorland's*. Therefore, if the medical records show that a hormonal contraceptive was prescribed for its primary purpose, that is, for contraception, rather than as treatment for menstrual irregularities; or if the medical records are silent as to the purpose of the prescription and the contraceptive use spanned the date on which the statute of limitations would have begun to run; the statute of limitations will not preclude the claim;
3. If the medical records indicate that the hormonal contraceptive was prescribed to treat menstrual irregularities, or if menstrual irregularities were a reason for the medical visit

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not violate the Constitution merely because it bars certain petitioners from bringing a claim before they knew, or even could have known, that their injuries were vaccine-related. *See, e.g.*, *Cloer v. Sec'y of HHS*, 85 Fed. Cl. 141, 150-51 (2008), *rev'd on other grounds*, 603 F.3d 1341, *aff'd en banc*, 654 F.3d 1322 (Fed. Cir. 2011); *Leuz v. Sec'y of HHS*, 63 Fed. Cl. 602, 607-12 (2005); *Wax v. Sec'y of HHS*, No. 03-2830V, 2012 WL 3867161, at *6-8 (Fed. Cl. Spec. Mstr. Aug. 7, 2012); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004); *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 753-54 (Ill. App. Ct. 2007).

[29] This decision expresses no opinion concerning the effect, if any, of contraceptive use on the question of causation in a POI case.

[30] Dr. Frankfurther indicated that non-hormonal copper IUDs may affect the volume of flow but do not influence the cycle length or frequency. Tr. at 422.

that resulted in the prescription of the contraceptive, then the undersigned will find that the menstrual irregularities were not "normal," but resulted in treatment, and therefore constituted a symptom for purposes of the statute of limitations.

C. Application of the Onset Symptom Criteria to the Present Case

Petitioner filed her petition on April 2, 2014. By extension, the petition is time-barred if "the first symptom or manifestation of onset" of her alleged vaccine injury, POI, occurred before April 2, 2011. Drs. Hersch and Hamiel both argue that Petitioner's menstrual irregularity is, standing alone, insufficient to constitute the date of the first symptom or manifestation of onset of Petitioner's POI due to the potential alternative explanations for the irregularity. Pet'r's Ex. 13 at 7, *Culligan*, ECF No. 47-1; Pet'r's Ex. 15 at 3, *Culligan,* ECF No. 53-1. Instead, they posit, the statute of limitations began to run in August 2012, when Petitioner experienced her final menstrual cycle.[31] Pet'r's Ex. 13 at 8, *Culligan*; Pet'r's Ex. 15 at 9, *Culligan*. Neither expert cites any medical literature in support of this conclusory assertion, which is directly refuted by the findings of the ACOG Opinion.

The undersigned finds that the first symptom of Petitioner's POI occurred no later than 2006, when, as Petitioner admits in her affidavit, she started taking hormonal birth control in order to regulate her menstrual cycle. Even Dr. Hamiel, Petitioner's expert, admitted at the hearing that she would do a work-up before placing an adolescent on contraceptives for regulating her menstrual cycle. Tr. at 112-14. That such irregularity resulted in treatment and would warrant further investigation necessarily means, as the undersigned previously explained, that the irregularity was a symptom—a symptom that we now know was the first sign or manifestation of POI.

In fact, given Petitioner's medical history, the date of Petitioner's first symptom could have been as early as 2001 or 2002, when Petitioner was prescribed OCPs after years of irregular menstruation. Indeed, the medical records from her December 2012 appointment reveal a striking pattern of generally irregular menstruation that only became regular with the support of OCPs. But ultimately, the undersigned finds that the 2006 date is the most clear-cut finding, as Petitioner's affidavit leaves no doubt that she was prescribed OCPs "to regulate" her menses.[32]

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[31] The undersigned assumes that Petitioner is asserting that the first symptom of her POI was amenorrhea. However, that would date, not from the date of her last menses, but four months after her last menses, or December 2012. *See* Nelson at 1.

[32] While the medical records from this time period indicate consistent irregularity and repeated prescription of OCPs, the undersigned finds that the records are devoid of sufficient information to make a finding either under the ACOG criteria or on the basis of an OCP prescription during that time.

In sum, the undersigned finds that Petitioner suffered menstrual irregularity in 2006, when she was prescribed hormonal birth control to treat that irregularity. This irregularity was the first symptom or manifestation of onset of Petitioner's alleged vaccine-caused injury, POI.

IV. CONCLUSION

Based on the foregoing analysis, the undersigned finds that the first symptom of Petitioner's injury was in 2006. Because that date precedes the statute of limitations deadline by four years, the undersigned concludes that Petitioner's claim is time-barred. Her petition therefore must be, and is hereby, **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[33]

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

[33] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.